

### **REMARKS**

Favourable reconsideration is respectfully requested.

The claims are 12 to 22.

The above Amendment is responsive to points set forth in the Official Action.

The above amendment to Claims 12, 19, 20, 21 and 22 inserts a proviso which excludes retinoic acid. The significance of this amendment will become further apparent from the remarks below.

Firstly, claims 12 and 13 and 19 to 22 have been rejected as anticipated by Mehta (US 5,811,119).

This rejection is respectfully traversed.

Mehta discloses therapeutic compositions of carotenoids encapsulated in liposomes or other lipid carrier particles and containing an intercalation promoter (which is a triglyceride) as an essential component. More specifically, and referring in particular to the claims, it relates to the use of liposomal compositions for intravenous administration containing all-trans retinoic acid for the treatment of cancer. The retinoic acid is present as a cytotoxic agent with reduced toxicity. Mehta is clearly concerned solely with targeting retinoic acid to cancerous cells.

In contrast, the present application relates to compositions and dispersions, together with methods for their preparation, which are generally suitable for use in creams and lotions for skin care. The compositions described in the present application are certainly not envisaged for intravenous use.

Applicant accepts that retinoic acid falls within the definition of a carboxylic acid, however, for this reason, the use of retinoic acid has now been specifically disclaimed by virtue of the aforementioned amendment to the claims of the present application.

The subject matter as now claimed in all of the claims of this application is clearly novel over and unobvious from the teaching of Mehta.

Claims 12 to 15 and 18 to 22 have been rejected under 35USC103(a) as unpatentable over Roux (US 6,103,259) or Hayward (US 5,585,109) in combination with the aforementioned Mehta.

Further, Claims 16 and 17 have been rejected under 35 USC103(a) over the aforementioned Roux or Hayward in combination with the aforementioned Mehta and either Touitou (US 5716638) or Ribier (US 5614215).

These rejections are respectfully traversed.

Mehta is thus the principal citation relied upon by the rejection which has combined this with various other prior art documents for the purpose of constructing an argument that the subject matter of the various aforementioned claims is obvious.

In response, as discussed above, Mehta is concerned with the specific use of retinoic acid and an intercalation promoter for the intravenous treatment of cancer. There is no teaching or suggestion in Mehta that the composition could be used topically. The Official Action has not indicated why a person skilled in the art would choose to regard Mehta as a starting point, or seek to combine it with other prior art documents, if their intention is to develop a composition of the type that is the subject of the present application and is intended for topical use.

In any event, there are a number of significant differences between the secondary references and the present application. These can be summarized as follows:-

Roux is concerned with providing a process for the preparation of liposomes without the use of an organic solvent. The two-stage process requires the use of a surfactant (of the type defined at column 2, lines 9 to 11) and an aqueous solvent. The presence of the surfactant is required in order to dissolve the sterol component. In contrast, and as is apparent from claim 19, the dry powder compositions of the present application are formed either by simply blending the powders together or by the use of an organic solvent and which is then removed. Most importantly, the use of surfactants is avoided in the present application.

Hayward relates to a cosmetic composition for delivering free salicylic acid and which comprises liposomes, salicylic acid, a water-soluble organic base and water as essential components. The presence of a water-soluble organic base is required. In contrast, the present application does not require the use of an organic base and, furthermore, does not require the presence of liposomes.

Touitou describes a liposomal composition for application to the skin and which results in

the transdermal passage of an active ingredient or in the introduction of such an agent into the skin. The essential components are said to be phospholipids, aliphatic alcohol, water and an active ingredient. The presence of the aliphatic alcohol is required in order to achieve the high degree of skin penetration that is claimed. In contrast, the compositions of the present application do not contain an alcohol component.

Ribier discloses a cosmetic composition for the simultaneous treatment of the surface and of deep layers of the skin. The composition comprises a first dispersion of lipid vesicles capable of entering the deep layers of the skin and a second dispersion of lipid vesicles capable of entering the surface layers of the skin. These two dispersions are kept separate. The presence of the two components is required. In contrast, the compositions of the present invention are a homogeneous mixture of the lipid assemblies.

The present invention is therefore novel and unobvious over the prior art alone or combined.

No further issues remaining, allowance of this application is respectfully requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact undersigned at the telephone number below.

Respectfully submitted,

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